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~~provided that if said oil-soluble oxygen-labile species is a retinoid, there is more than one oxygen-labile species present in said composition.~~

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5. Compositions according to claim 1 wherein said oil-soluble oxygen-labile species are selected from one or more of the group consisting of retinoids, cholecalciferol, vitamin K and tocopherol and their derivatives, provided that if said oil-soluble oxygen-labile species is a retinoid, there is more than one oxygen-labile species present in said composition.

REMARKS

This Amendment is respectfully submitted in response to the Office Action rendered January 10, 2000. An Information Disclosure Statement and accompanying references are also respectfully submitted herewith.

The claims have been amended in accordance with applicants' provisional election to delete reference to "water-soluble oxygen labile species" without prejudice. Claims encompassing such species will be filed in a divisional application presently. The clause --provided that if said oil-soluble oxygen-labile species is a retinoid, there is more than one oxygen-labile species present in said composition-- has been added to claims 1 and 5. The foregoing amendments to the claims find basis in the Specification at page 4, line 23 through page 5, line 2 and at page 16, line 1 (Example 6) through page 17, line 8.

The Office Action of January 10, 2000 has required to one of the following inventions under 35 U.S.C. 121:

I. Claims 1-15, drawn to compositions containing oil-soluble and/or water-soluble oxygen-labile species and stabilizer compounds.

II. Claim 16, drawn to a method of stabilizing oil-soluble or water-soluble oxygen-labile compositions.

Applicants respectfully traverse this requirement. Applicants respectfully submit that searching both groups would not be an undue burden upon the Patent Office and that they may be searched together. Notwithstanding, applicants provisionally elect the invention set forth in Group I above for prosecution.

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The Office Action of January 10, 2000 further requires applicants, at pages 3-6, to elect a sub-genus and a species therefrom for prosecution on the merits. Applicants respectfully traverse this requirement, on the ground that, although the structures referred to in the Office Action at pages 2-3 are different, they are similar in that they are known as oil-soluble, oxygen-labile species. Moreover, the thio-containing species set forth at page 4-5, including sulfites, metabisulfites, glutathione and cysteine derivatives are all known thio-containing species and therefore searching would not pose an additional burden on the Patent Office. Notwithstanding this traverse, applicants provisionally elect the sub-genus of "oil-soluble" oxygen labile species, corresponding to claims 1, 2, 5-13 and 15. Further, they provisionally elect the species of compositions comprising retinol, ascorbic acid and tocopherol with N-acetyl cysteine, corresponding to claims 1, 2, 5-13 and 15.

Claims 1, 2, 5-13 and 15 were rejected under 35 U.S.C. 112, first paragraph on the ground that the specification is enabling for water-in-oil emulsion compositions and "does not reasonably provide enablement for compositions where n-acetylcysteine is present as the sole stabilizer". The Office Action also contends that the specification

... does not enable any person skilled in the art to which it pertains... to practice the invention commensurate in scope with these claims. The specification examples all teach compositions that result in water-in-oil emulsions where n-acetylcysteine is present in combination with lactoferrin or ascorbic acid, each of which [is] acting as a[n] antioxidant stabilizer. The claims, however, teach the ability to make and use a stable composition where n-acetylcysteine is the sole stabilizer in combination with the oil-soluble oxygen labile species retinoids. In addition, the claims embrace compositions that are non-emulsions, while the scope of the teachings in the specification is limited to emulsion type compositions. [Office Action, p. 8]

Applicants respectfully request reconsideration of this rejection in light of the amendment to the claims and the ensuing discussion. First, Example 1 demonstrates the addition of N-acetyl cysteine alone as a stabilizer for ascorbic acid, an oxygen-labile species. Thus, the claims are fully enabled by the Specification. In addition, the Specification clearly states that thio-containing compounds may be utilized alone as stabilizers (see, e.g., page 3, l. 15-page 4, l. 2 and page 4, l. 26-29). Applicants are not aware that there is a requirement that a specific example be provided for each particular element of the claims in order to comply with 35 U.S.C. 112, first paragraph.

With regard to the ability to make and use a stable composition where N-acetyl cysteine is the sole stabilizer in combination with the oil-soluble oxygen labile species retinoids, the claims have been amended to indicate that, when the oxygen-labile species is a retinoid, more than one oxygen-labile

species is present in the composition, including ascorbic acid, which is defined as a water-soluble oxygen-labile species in the specification at page 3, line 5. This amendment is supported in the Specification in Example 6. Both retinoids and ascorbic acid are known to be oxygen-labile and relatively unstable in compositions. As set forth in the specification, "[o]ne of ordinary skill in the art would expect that vitamins A and C together would not be stable as Vitamin C tends to sacrifice itself to stabilize Vitamin A." The Office Action also states that "The claims... teach the ability to make and Thus, the amendment to the claims, applicants submit, should address the concerns of the Office Action and reconsideration of this rejection is respectfully requested.

As to the question of enablement of "non-emulsions" in the claims, applicants respectfully direct the Patent Office to page 5, lines 13-17 of the Specification:

The compositions of this invention may be utilized in dosage forms suitable for cosmetic or pharmaceutical use. For example, the compositions of this invention may be made in the forms of emulsions, creams, lotions, gels, essences, milks, toners, hydroalcoholic solutions, multivesicular systems, suspensions, patches, masks, sticks and other dosage forms suitable for therapeutic use, including oral administration forms.

Thus, there is ample support in the Specification for the use of the basic invention in many types of compositions. Methods of making these compositions are known to those of skill in the art. Again, the claims should not be limited to "emulsions" alone if others make, use or sell different types of compositions containing the basic elements of the claims. Claims are not interpreted to be narrowly limited to specific examples set forth in the Specification. The compositions of applicants' invention relate to a stabilization system rather than the specific physical form of the composition. Applicants therefore respectfully request reconsideration of the rejection under 35 U.S.C. 112 on this ground.

Claims 1, 2, 5-13 and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Reed et al. Applicants respectfully request reconsideration of this rejection in light of the foregoing amendments to the claims and the ensuing remarks.

The basis for this rejection is stated in the Office Action to be the following:

REED teaches the incorporation of retinoids in water-in-oil emulsions (page 1), and the susceptibility of the retinoid to oxidation in water-in-oil emulsion and hence a short shelf-life of the emulsion compositions (page). REED also teaches the use of antioxidants to improve the oxidative stability of retinoid-containing water-in-oil emulsions (page 2). Finally REED teaches the use of n-acetylcysteine in the composition (page 10). Thus REED teaches a water-in-oil emulsion composition encompassing tretinoid and n-acetylcysteine for use in the skin care industry and therefore claims 1, 2, 5-13, and 15 are anticipated. [Office Action, p. 9]

The reference referred to in the Office Action as "Reed et al." (applicants respectfully note that "Reed" is the name of the applicant's agent; Robinson et al. are referred to as inventors) describes topical water-in-silicone retinol-containing compositions. Reed refers to the stabilization of retinol present in the compositions without other oxygen-labile species or antioxidants. In fact, Reed teaches that the stabilizing entity in the described compositions is the water-in-silicone emulsion system:

The select emulsion systems comprise a discontinuous aqueous phase dispersed in a continuous silicone phase, wherein the continuous silicone phase comprises between about 50% and about 99.9% by weight of organopolysiloxane oil and less than about 50% by weight of a non-silicone oil. **It has been found that the polyorganosiloxane oil component, when incorporated into the water-in-silicone emulsion system described herein, provides topical retinoids with more oxidative stability over extended periods of time than comparable water-in-oil emulsions containing lower concentrations of the polyorganosiloxane oil.** [Reed, page 2, line 12-20] (emphasis added)

Thus, Reed addresses the problem of stability of retinol by utilizing a specific water-in-silicone composition alone, without the necessary addition of antioxidants or other species. Moreover, Reed mentions N-acetyl cysteine only as an additive for the purpose of improving the appearance of the skin [Reed, page 10, lines 23-33]. Thus, Reed does not disclose or teach compositions containing N-acetyl cysteine as a stabilizer in skin care compositions.

Furthermore, the claims of applicants' application, as amended, require the presence of other oxygen-labile species in the compositions of the invention when an oil-soluble antioxidant is retinol. Reed, therefore, would not anticipate the claims as amended, as it does not disclose or suggest the combination of retinol, additional oxygen-labile species and a stabilizer. In view of the foregoing amendments to the claims and discussion, applicants respectfully request reconsideration of the rejection under 35 U.S.C. 102(b).

Applicants also respectfully note that the Reed reference teaches away from using antioxidants in compositions containing retinol:

One attempt at improving the oxidative stability of retinoid-containing water-in-oil emulsions involves the use of antioxidants in combination with the retinoid. These antioxidants are especially useful when used in combination with highly oxidation-sensitive retinoids such as retinol. **Although antioxidants would seem to improve oxidative stability of certain retinoids in these emulsion systems, and even permit the use of retinol in a water-in-silicone emulsion system, these added materials can increase raw material costs and**

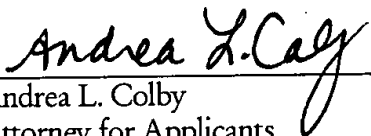
introduce additional chemical and physical compatibility issues. [Reed, p. 2, l. 1-9]
(emphasis added)

The other references cited but not relied upon have been reviewed and applicants deem them no more pertinent to the subject matter of the claims than that cited and relied-upon.

Applicants respectfully submit an Information Disclosure Statement and accompanying references concurrently herewith for review by the Patent Office. The references not in the English language will be translated and submitted as soon as possible.

Applicants respectfully request reconsideration of the rejections set forth in the Office Action of January 10, 2000 in light of the foregoing amendments and discussion. An early allowance is earnestly solicited.

Respectfully submitted,


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